

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231*H/N*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/186,810 11/05/98 CARLYLE

W S16.12-0052

QM22/0313

PETER S DARDI
WESTMAN CHAMPLIN AND KELLY
SUITE 1600 INTERNATIONAL CENTRE
900 SECOND AVENUE SOUTH
MINNEAPOLIS MN 55402-3319

EXAMINER

PRERILIC.P

ART UNIT	PAPER NUMBER
----------	--------------

3738

12

DATE MAILED:

03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/186,810	Applicant(s) Carlyle et al
	Examiner Paul Prebilic	Group Art Unit 3738

Responsive to communication(s) filed on Feb 15, 2001.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1, 3, 4, 8-17, and 28 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1, 3, 4, 8-17, and 28 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 3738

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 15, 2001 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4, and 8-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the newly added language "two aldehyde functional groups that are transformed into other functional groups" lacks clear original support because similar language and structure cannot be found in the original disclosure, particularly for the portion underlined. For this reason, the Examiner posits that this language may constitute new matter. An alternative rejection under 35 USC 112, second paragraph is given below to address the situation where Applicant can show that the claimed subject matter has inherent support.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 3738

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, and 8-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Note the objected to language set forth in the 35 USC 112, first paragraph rejection above. There is no clear antecedent basis in the specification for the claimed language even if it is found to be inherent. Alternatively, it is not clear what the language "transformed into other functional groups" means and how it is to be interpreted.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 8, 9, 11, 12, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahalan et al (US 5,308,641) wherein the glutaraldehyde crosslinking agent attaches to the growth factor biomolecule and to the spacer attached to the substrate; see the whole document, especially the abstract, column 4, lines 20-43 and column 6, lines 8-28.

Claims 1, 3, 4, 11, 14, 15, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Rodman (US 5,606,026). Rodman anticipates the claim language where the 2 mm strips are the substrate as claimed; see the whole document, especially column 16, lines 28-39.

Art Unit: 3738

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al (US 5,308,641) in view of Goldstein (US 5,613,982). Cahalan et al disclose the use of human tissue and animal tissue as the implant substrate material but fail to disclose the specific types of animal tissue therefor. Goldstein, however, teaches that it was known to use porcine tissue for similar implants. Hence, it is the Examiner's position that it would have been obvious to use porcine tissue as the tissue substrate of Cahalan et al in order to reduce the cost of the implant and in order to reduce the risk of disease transmission to human beings upon implantation.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al (US 5,308,641) in view of Robertson et al (US 3,755,042). Cahalan et al meet the claim language except for the sterilizing and packaging of the implant as claimed. Robertson et al, however, teaches that sterilizing and packaging of medical materials for distribution has been known to the art. Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to sterilize and package the Cahalan et al device so that patients all over the world could benefit from it.

Art Unit: 3738

Claims 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al (US 5,308,641) in view of Bayne et al (EP 0476983).

With regard to claim 13, Cahalan et al fail to disclose the use of VEGF even though many other growth factors are listed for use therewith. Bayne et al, however, teaches that the claimed VEGF growth factor has been known and used in the same art in a very similar fashion. Hence, it is the Examiner's position that it would have been obvious to an ordinary artisan to use VEGF as the growth factor of Cahalan et al so that such an implant could be successfully implanted inside the vascular regions of the body.

With regard to claim 16, Cahalan et al do not disclose the process of culturing cells onto the implant as claimed. Bayne et al teaches that it was known to the art to do so at the time the present invention was made. Hence, it is the Examiner's position that it would have been obvious to pre-seed or culture cells onto the Cahalan et al implant for the same reasons Bayne et al does the same and in order to control the types of cells which grow in the implant.

Response to Arguments

Applicant's arguments with respect to all the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Art Unit: 3738

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
Art Unit 3738